

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER  
WHEN USED ACCORDING TO DIRECTIONS**

**3981. Misbranding of vaginal suppositories. U. S. v. 131 Boxes \* \* \*. (F. D. C. No. 34396. Sample No. 39888-L.)**

**LIBEL FILED:** December 24, 1952, Southern District of California.

**ALLEGED SHIPMENT:** On or about September 29, 1952, by the Dr. J. A. McGill Co., from Chicago, Ill.

**PRODUCT:** 131 boxes of *vaginal suppositories* at Los Angeles, Calif. Examination showed that the product contained approximately 47 percent ammonium alum and 10.6 percent borax in a fatty base. Each box contained a copy of a leaflet entitled "Dr. J. A. McGill Co.'s Suppositories."

**LABEL, IN PART:** (Box) "Contents 6 Suppositories \* \* \* Orange Blossom Suppositories \* \* \* Alum - Borax - Petrolatum \* \* \* Dr. J. A. McGill Co. \* \* \* Chicago 16, Ill."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the statement appearing in the labeling of the article "For Simple Irritations Of The Vaginal Tract" was false and misleading. The statement represented and suggested that the article was an adequate and effective treatment for diseases of the vaginal tract which are manifested by irritation of the vaginal tract, whereas the article was not an adequate and effective treatment for these diseases.

Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Directions Remove tinfoil at bedtime, insert one suppository in vagina and with your finger push it up as far as you can. Let it remain there undisturbed for three days. Then at night take a douche of warm water, and on the evening of the second day apply again as above making the application every five days excepting at monthly periods, allowing four days for the periods, then apply the suppository every five days."

**DISPOSITION:** January 26, 1953. Default decree of condemnation and destruction.

**3982. Misbranding of Mam-Zelle syringe and Mam-Zelle tablets. U. S. v. 11 Cartons, etc. (F. D. C. No. 34656. Sample No. 18577-L.)**

**LIBEL FILED:** February 17, 1953, District of Arizona.

**ALLEGED SHIPMENT:** On or about November 29, 1952, by the Barclay Pharmaceutical Products Co., from Pasadena, Calif.

**PRODUCT:** 1 carton containing 12 12-tablet bottles of *Mam-Zelle tablets*, and 11 cartons, each containing 2 packages, and each package consisting of a cardboard box containing 1 *Mam-Zelle syringe* and 1 12-tablet bottle of *Mam-Zelle tablets*, at Phoenix, Ariz. There were enclosed in each package a circular designated "For women Strictly personal," and a circular designated "How To Use *Mam-Zelle* Effervescent Feminine Hygiene Syringe Unit."

The *Mam-Zelle syringe* consisted of a two-piece plastic cylinder which was closed except for a valve-operated exit tube which connected through a short piece of rubber tubing to a plastic nozzle having eight small holes at the sides and one small hole at its tip. In operation, the plastic cylinder was charged by filling with water and placing one of the *Mam-Zelle tablets* in position. After the assembling of the cylinder, the water and tablet were brought into contact whereby the effervescing-type tablet dissolved with the liberation of

carbon dioxide gas which created a pressure inside the cylinder. When the release valve was pressed, the liquid emerged under pressure from the cylinder and passed through the rubber tubing into the plastic nozzle whence it emerged in streams from the openings of the nozzle.

**LABEL, IN PART:** (Box) "Mam-Zelle Effervescent The New Way to Feminine Daintiness \* \* \* Feminine Hygiene Syringe Unit. This package contains syringe and bottle of 12 Mam-Zelle tablets (Sodium Chloride & Boric Acid.) Use as directed in enclosed circular. Caution: Use only one tablet at a time."

**NATURE OF CHARGE:** Misbranding, Section 502 (j), the device and the tablets were dangerous to health when used in the dosage and with the frequency and duration recommended in the labeling since the applicator nozzle which was to be inserted into the vagina had an exit hole at its very tip, thus enabling part of the liquid to be directed into the cervical opening with harmful results, and because of the excessive pressure in the device, the emerging liquid was applied with sufficient force to cause damage to the genital tract.

**DISPOSITION:** March 24, 1953. The Barclay Pharmaceutical Products Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the products be released under bond to be brought into compliance with the law, under the supervision of the Federal Security Agency. The devices were dismantled and rebuilt to correct the danger complained of.

### **VIOLATIVE SALES OF PRESCRIPTION DRUGS**

**3983. Misbranding of diethylstilbestrol tablets, dextro-amphetamine sulfate tablets, methyltestosterone tablets, and conjugated estrogens (equine) tablets. U. S. v. Nathan A. Riemer (Riemer Pharmacy), and Sidney Koach. Pleas of nolo contendere. Fines of \$250 against Defendant Riemer and \$50 against Defendant Koach. (F. D. C. No. 34311. Sample Nos. 35931-L, 35934-L, 36203-L, 36228-L.)**

**INFORMATION FILED:** February 9, 1953, Northern District of Ohio, against Nathan A. Riemer, trading as Riemer Pharmacy, Cleveland, Ohio, and Sidney Koach, an employee of the pharmacy.

**NATURE OF CHARGE:** On or about May 16 and 24 and June 10 and 11, 1952, while a number of *diethylstilbestrol tablets, dextro-amphetamine sulfate tablets, methyltestosterone tablets, and conjugated estrogens (equine) tablets* were being held for sale at the Riemer Pharmacy, after shipment in interstate commerce, various quantities of the drugs were dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such dispensing was contrary to the provisions of Section 503 (b) (1) and resulted in the drugs so dispensed being misbranded.

Nathan A. Riemer was charged with causing the act of dispensing in each of the four counts of the information, and Sidney Koach was joined as a defendant in one of the counts.

**DISPOSITION:** March 2, 1953. Pleas of nolo contendere having been entered by the defendants, the court fined Defendant Riemer \$250 and Defendant Koach \$50.